

U.S. Patent Application No. 10/681,352
Amendment dated November 17, 2006

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REMARKS/ARGUMENTS

Reconsideration and continued examination of the above-identified application are respectfully requested.

Claims 1-24 have been canceled. New claims 25-28 have been added. Support for the new claims can be found, for example, at pages 18, 19, 22, and 80-82 and Figs. 1-3, 85-89, and 90-104 of the present application. Accordingly, no questions of new matter should arise and entry of this amendment is respectfully requested.

Applicant notes with appreciation the telephone interview with Applicant's representative, Examiner Noakes, and Supervisory Examiner Weber on November 9, 2006. In the interview, the nature of the invention enabled by the specification was discussed. In particular, it was pointed out that the specification contained the results of numerous genetic tests from a multitude of cancer patients, and as such, the specification was not only directed to *in vitro* methods.

The Examiners indicated that a claim directed to using statistical methods to correlate cancer treatments with the results of a genetic analysis of specific diversity positions, of certain cancer-related genes, appeared to be a novel approach to cancer treatment. The Examiners also indicated that limiting the claims to stomach cancer patients, and further limiting the claims to the specific cancer treatments recited in the specification, would most likely also render the claims enabled in view of the specification. It was also pointed out that the entire sequences of the genes recited in the specification did not need to be recited in the specification, for enablement of the proposed claims, because only certain diversity positions of the genes in question were being analyzed. As such, the amino acids encoded at these diversity positions can be correlated with cancer treatments without the need to compare the entire genetic sequence

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with a reference sequence.

The Examiners indicated that claims amendments would not be entered after final, and that a Request for Continued Examination or continuation would be needed.

Claim of Priority

At page 2 of the Office Action, the Examiner indicates that the benefit of priority has not been granted because certified copies of the two foreign applications filed in Japan have not been filed.

In response, the applicants are obtaining certified copies of the two Japanese priority documents. The applicants have made a claim to priority at the time the application has been originally filed and will perfect this claim shortly. The applicants appreciate the Examiner's comments regarding this matter.

Objection to Claims 2, 12, 14, 21, and 24

At pages 3 and 5 of the Office Action, the Examiner maintains that claims 2, 12, 14, 21 and 24 are dependent claims of evaluating methods for screening a "cancer treatment medicine" (see claim 1) and evaluating "anticancer treatments" or "cancer treatments" (see claims 11 and 13). The Examiner objects to the phrase "wherein cancer is analyzed by distinguishing stomach cancer from other cancers" and states that the phrases are confusing and lack a correlation step of how to distinguish stomach cancer from any other type of cancer. The Examiner states that the arguments filed May 5, 2006 have been fully considered but are not persuasive. For the following reasons, this objection is respectfully traversed.

The language objected to by the Examiner would be clear to one skilled in the art,

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especially in view of the present application. However, to assist the Examiner, new claims 24-28 do not recite the language objected to by the Examiner and these claims would be clear to one skilled in the art. Accordingly, this objection should be withdrawn.

Rejection of Claims 1-6, 11-14, and 19-24 Under 35 U.S.C. §112, First and Second Paragraphs

At pages 3, 6, and 9 of the Office Action, the Examiner rejects claims 1-6, 11-14 and 19-24 under 35 U.S.C. §112, first paragraph, for failing to comply with the written description and enablement requirements. The Examiner maintains the enablement rejection of claims 1-10 as recited in the previous Office Action, in section 20. The Examiner states that the Applicant's previous amendments have been fully considered but are not persuasive.

In particular, the Examiner rejects the claims and asserts the following:

1) There is no disclosure in the specification that would indicate the Applicants were in possession of the three-dimensional structure of even a single species out of the thousands of possible for each polypeptide encoded in an allelic variant having changes at the cited positions; and

2) while the Applicants have identified potential variation sites, the claims are still not supported in the written description because there is no correlation between the structure and function of the variation sites.

The Examiner at page 11 also rejects claims 1-6, 11-14, and 19-24 under 35 U.S.C. §112, second paragraph. The Examiner asserts in this rejection that exact sequences are necessary and that it is unclear what sequence is being referred to in the claims, when the claims, according to the Examiner, suggest a reference point. For the following reasons, these rejections are respectfully traversed.

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New claims 25-28, have been added to even more particularly point out the nature of the claimed invention. As discussed at the telephone interview of November 9, 2006, the new claims are enabled in view of the present specification. In particular, the presently claimed inventions are enabled because the amino acids encoded at the recited diversity positions, which are correlated with cancer treatments having the greatest statistical probability of prolonging patient survival, are recited in the specification. *See*, for example, pages 18, 19, 22, and 80-82 and Figs. 1-3, 85-89, and 90-104. Only this information is needed to practice the presently claimed invention. Therefore, there is no need to compare the entire genetic sequences of the recited genes, with a reference sequence. Furthermore, the sequences of the recited genes were known to one skilled in the art, at the time the present application was filed. In light of the new claims, this rejection should be withdrawn.

Rejection of Claims 11-14 Under 35 U.S.C. §103(a) – Davies et al. in view of Lee et al.

At pages 5 and 10 of the Office Action, the Examiner maintains the rejection of claims 11-14 under 35 U.S.C. §103(a) as being obvious over Davies et al. (J. Clinical Oncology, vol. 19, pp. 1279-1287, 2001) in view of Lee et al. (Gastroenterology, vol. 111, pp. 426-432, 1996). The Examiner was not convinced that the rejection should be withdrawn because independent claims 1 and 11 now recite specific amino acids positions for which at least one position of HLA DQB1*, DRB1*, and DPB1* were amended in the response to the previous Office Action. For the following reasons, this rejection is respectfully traversed.

Clearly, Davies et al. and Lee et al. do not teach or suggest a method for determining treatments for a cancer patient, which involves determining what amino acids are encoded by one or more specific positions of the HLA DQB1* gene of the patient, determining what amino acids are

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encoded by one or more positions of the DRB1* gene of the patient, and determining what amino acids are encoded by one or more positions of the DPB1* gene of the patient, wherein the particular positions are recited in the claims and wherein the method involves correlating the amino acids encoded at these positions with a cancer treatment having the greatest statistically significant probability of prolonging the patient's survival, wherein the cancer treatment is immunotherapy, chemotherapy, resection, or a combination thereof. Davies et al. and Lee et al. have no appreciation for correlating the specific amino acids encoded at these positions and the fact that by doing so, one can correlate with a cancer treatment. Therefore, for these reasons, this rejection should be withdrawn.

Rejection of Claims 1-6 Under 35 U.S.C. §103(a) – Davies et al. in view of Lee et al., Toh et al., and Gibbs et al.

At page 5 of the Office Action, the Examiner rejects claims 1-6 under 35 U.S.C. §103(a) as being obvious over Davies et al. (J. Clinical Oncology, vol. 19, pp. 1279-1287, 2001) in view of Lee et al. (Gastroenterology, vol. 111, pp. 426-432, 1996), Toh et al. (Protein Engineering, vol. 11, pp. 1027-1032, 1998), and Gibbs et al. (Science, vol. 287, pp. 1969-1973, 2000). The details of the rejection are recited in the previous Office Action on pages 25-27, Section B. For the following reasons, this rejection is respectfully traversed.

As stated, Davies et al. and Lee et al. do not teach or suggest a method for determining treatments for a cancer patient, which involves determining what amino acids are encoded by one or more positions of the HLA DQB1* gene of the patient, determining what amino acids are encoded by one or more positions of the DRB1* gene of the patient, and determining what amino acids are encoded by one or more positions of the DPB1* gene of the patient, wherein the particular positions are recited in the claims and which involves correlating the amino acids encoded at these positions

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with a cancer treatment having the greatest statistically significant probability of prolonging the patient's survival, wherein the cancer treatment is immunotherapy, chemotherapy, resection, or a combination thereof. Davies et al., Lee et al., Toh et al., and Gibbs et al. have no appreciation for correlating the specific amino acids encoded at these positions and the fact that by doing so, one can correlate with a cancer treatment. Therefore, for these reasons, this rejection should be withdrawn.

CONCLUSION

In view of the foregoing remarks, the applicant respectfully requests the reconsideration of this application and the timely allowance of the pending claims.

If there are any other fees due in connection with the filing of this Amendment, please charge the fees to Deposit Account No. 50-0925. If a fee is required for an extension of time under 37 C.F.R. §1.136 not accounted for above, such extension is requested and should also be charged to our Deposit Account.

Respectfully submitted,



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